

## **II. Remarks**

### **A. Status of the Claims**

Claims 2-10 will be pending after entry of this amendment. Claims 1 and 35 have been canceled without prejudice. Claims 11-34 and 36-54 were previously canceled. Claims 3 and 9 have been amended without prejudice. Applicant submits that no new matter has been added by virtue of this amendment.

### **B. Claims Rejections Under 35 U.S.C. § 103(a)**

In the Final Office Action, claims 1-10 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed et al. (WO 98/16645). In making the rejection, the Examiner referred to Applicant's August 7, 2007 Response and stated that "Applicant's statements [] actually state that polypeptide MTBN4 is encoded by the genome of BCG strain of *M. bovis*. This is a contradiction to the newly inserted wording which says that polypeptide 'is not encoded' by the genome of BCG strain *M. bovis*". (Emphasis in original). The Examiner further stated that "[u]ntil such time as applicant can explain this contradiction, the rejection remains because the cited reference does teach polypeptide MTBN4 sequence and as stated in the original rejection explanation, because the protein sequence was known, it would have been obvious to one of ordinary skill in the art to instantly envision a DNA which encodes the known amino acid sequence."

This rejection is traversed. Applicant respectfully submits that the Examiner is mischaracterizing the statements made in the August 7, 2007 Response. Applicant respectfully points out that the August 7, 2007 Response stated that "BCG is derived from *Mycobacterium bovis*, the genome of which does encode MTBN4." Thus, Applicant is stating that the genome of *Mycobacterium bovis* encodes MTBN4, and is not stating that the strain of BCG encodes MTBN4, as alleged by the Examiner. Applicant's August 7, 2007 Response further stated that "in the absence of information to the contrary, one ordinarily skilled in the art would consider it likely that MTBN4 was also encoded by the genome of BCG". This statement refers to the fact that, in the state of the art at the time

Reed et al. was filed, it is likely that one of skill in the art would mistakenly assume that the strain of BCG would encode MTBN4 because *Mycobacterium bovis* encodes MTBN4. However, as can be seen in Table 1 at page 567 of Talbot et al. "PCR Identification of *Mycobacterium bovis* BCG", *J of Clin Microbio* (Mar 1997) **35**:3 pp 566-569 (attached as Exhibit A), there are multiple strains of *Mycobacterium bovis*, some of which are BCG and some of which are non-BCG. Therefore, it is possible for MTBN4 to be encoded by *Mycobacterium bovis* (non-BCG) and not *Mycobacterium bovis* BCG.

Further, for reasons of record, Applicant submits that, in view of Reed et al., one of skill in the art would not be motivated to make the present invention in accordance with the current claims.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) over Reed et al. be removed.

### **C. Claim Rejections Under 35 U.S.C. § 112**

In the Final Office Action, claims 1-10 and 35 were rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner stated that "as evidenced by the sequence search, and applicant's own statements [] the polypeptide MTBN4 is encoded by the genome of BCG strain of *M. bovis*."

This rejection is traversed. For the reasons discussed *supra*, Applicant submits that the statements made in the August 7, 2007 Response were mischaracterized by the Examiner, and reassert that MTBN4 is not encoded by the genome of BCG strain of *M. bovis*.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph be removed.

### **III. Conclusion**

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-6162. The undersigned also may be contacted via e-mail at [epietrowski@lowenstein.com](mailto:epietrowski@lowenstein.com). All correspondence should be directed to our address listed below.

### **AUTHORIZATION**

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,  
Lowenstein Sandler PC

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By: Elizabeth Pietrowski  
Attorney for Applicants  
Registration No. 52,121

DOCKET ADMINISTRATOR  
LOWENSTEIN SANDLER PC  
65 Livingston Avenue  
Roseland, NJ 07068  
General Tel.: 973-579-2500